



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/477,236

01/04/2000

JASON T. LENZ

S63.2-7531

8883

490

7590

01/15/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/477,236

Applicant(s)

LENZ, JASON T.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed on paper number 15 have been fully considered but they are not persuasive. For a person of ordinary skill in the art, a coating cannot be simultaneously uniform and non-continuous. If a coating is non-continuous, it must have a different thickness around the circumference of the balloon, and therefore, it cannot be uniform as described in the claims. The independent claims are so broad, that it is not clear for a person of ordinary skill in the art, whether the coating is uniform or non-continuous.

Claim Rejections - 35 USC § 112

Claims 1, 3, 23 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For a person of ordinary skill in the art, a coating cannot be simultaneously uniform and non-continuous. If a coating is non-continuous, it must have a different thickness around the circumference of the balloon, and therefore, it cannot be uniform as described in the claims. The independent claims are so broad, that it is not clear for a person of ordinary skill in the art, whether the coating is uniform or non-continuous.

In claim 1, the term medical device lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3763

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Porter, et al., in view of Muni and (Sahatjian or Wang , et al.)**. The referenced patent discloses an insertable medical device having a protective surface coating, the coating comprising a polymer selected from a group consisting of thermoplastic polymers and thermosetting polymers, and the coating being non-continuous on the medical device. As argued by the applicant, Porter, et al., does not disclose "a coating which is non-continuous". However, the use of non-continuous coatings on exterior surfaces of catheters or cannulas is conventional in the art as taught by Muni. In column 5, line 51, Muni defines the term "non-uniform" coating as (1) a coating that is variable in thickness along the circumference or length of the body, or (2) to a coating which covers the body in some areas, but not at all in others (see figure 4B). Based on the teachings of the Muni patent, it would have been obvious to modify Porter, et al., with a non-continuous coating since said modification is well known in the art, and therefore, an obvious design alternative.

Additionally, in response to applicant's comments, examiner introduces **Sahatjian or Wang , et al.**, to demonstrate that it is conventional and well known in the art to use coatings in dilation balloons. Whether the coating is applied to a stent, a catheter shaft, or a catheter balloon, the coating is intended to facilitate the introduction of the particular surgical instrument into the area of application in the body. Therefore, the application of coatings to various surgical instruments would be considered by a person of ordinary skill in the art, an obvious design alternative.

Art Unit: 3763

Finally, **Sahatjian or Wang , et al.**, also demonstrate that the coating can be uniform throughout the body of the balloon catheter.

Claims 1, 3-8 and 23-29 rejected under 35 U.S.C. 103(a) as being unpatentable over **Yang, et al., in view of Porter, et al., and Muni**. The Yang, et al. patent discloses a medical balloon insertable in the body having a uniform protective coating. Yang, et al., does not disclose the use of thermosetting polymers or non-uniform coating patterns. However, Porter, et al., discloses an insertable medical device having a protective surface coating, the coating comprising a polymer selected from a group consisting of thermoplastic polymers and thermosetting polymers, and the coating being non-continuous on the medical device. Additionally, in column 5, line 51, Muni defines the term "non-uniform" coating as (1) a coating that is variable in thickness along the circumference or length of the body, or (2) to a coating which covers the body in some areas, but not at all in others (see figure 4B).

Based on the teachings of the Porter, et al., and Muni patents, it would have been obvious to modify the balloon coating in Yang, et al., with a polymer selected from a group consisting of thermoplastic polymers and thermosetting polymers and a non-continuous coating since said modifications are well known in the art, and therefore, are considered obvious design alternatives.

Conclusion

In view of the new grounds of rejection, this action is not final. Any inquiry concerning this communication or earlier communications from the examiner should be

Art Unit: 3763

directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a large, stylized flourish at the end.

Primary Patent Examiner